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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,307	10/14/2003	Martin Bluggel	B0004/7115	9843

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EXAMINER	
HYUN, PAUL SANG HWA	
ART UNIT	**PAPER NUMBER**
1797	
MAIL DATE	**DELIVERY MODE**
12/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/685,307	BLUGGEL ET AL.	
	Examiner	Art Unit	
	Paul S. Hyun	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *13-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

REMARKS

Claims 1-17 remain pending with claims 13-17 being withdrawn. Applicants have affirmed the election of claims 1-12 made on June 22, 2007 pursuant to a restriction requirement.

Amendments to claims 1, 8 and 12 have been acknowledged.

The claim objection cited in the previous Office action has been withdrawn in light of the amendment.

Claim rejections under 35 U.S.C. section 112 cited in the previous Office action have been withdrawn in light of the amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims **8 and 12** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "the mass spectrometric analysis". There is insufficient antecedent basis for this limitation in the claim. It has never been established that the sample is subjected to mass spectrometric analysis.

Claim 12 recites a means for conducting the preparations for mass spectrometric analysis of the separated samples. However, the claim does not actually recite the step

of conducting a mass spectrometric analysis of the separated samples. Therefore, it is unclear what method step claim 12 is attempting to further limit.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **1-3, 7 and 8** are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (US 2002/0139751 A1).

Zhang et al. disclose an electrospray device comprising a capillary column and a microchip array arranged in a series (see Figs. 5-8). The device can be coupled to a mass spectrometer (see [0013]) to identify proteins (see [0048]). The device can be used to conduct two-dimensional chromatography if the capillary column and the microchip array comprise different affinity adsorbents therein (see [0072]). Specifically, if two-dimensional chromatography is to be conducted, the capillary column is packed with a porous polymer monolith, and the channels of the microchip array are packed with a different porous polymer monolith that is covalently bound to the surfaces of the channels via alkyl groups. The capillary column serves as an ion-exchange column that separates a sample mixture into fractions based on charge, and the microchip array serves as hydrophobic adsorption columns. Alternatively, instead of using porous polymer monoliths, the two-dimensional chromatography can be formed using two different types of affinity ligands (see [0071]). The sub-fractions can be further

processed (e.g. proteolysis digestion using a endoprotease) prior to analyzing the sub-fractions with the mass spectrometer (see [0070]).

Claims **1-3, 5, 6, 11 and 12** are rejected under 35 U.S.C. 102(b) as being anticipated by LaDine et al. (US 2002/0068366 A1).

LaDine et al. disclose a method for conducting two-dimensional chromatography to separate a mixture of peptides (see [0039]). The two-dimensional chromatography can be carried out using microplates wherein the wells of the microplates are loaded with magnetic particles derivatized with functional groups configured to bind the analyte of interest. A first microplate is used to separate the sample mixture into discrete fractions. The fractions are then further separated into sub-fractions using a second microplate. The sub-fractions can then be analyzed using mass spectrometry. The reference discloses that the procedural steps for conducting the two-dimensional chromatography can be facilitated by using a robotic pipette (see [0029]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim **4** is rejected under 35 U.S.C. 103(a) as being unpatentable over LaDine et al. in view of Hammen (US 5,240,602).

LaDine et al. do not disclose the step of coating the inner surface of the wells of the microplates with substance-binding layers. Rather, LaDine et al. disclose the use of functionalized magnetic particles disposed in the wells to bind the analyte of interest.

Hammen discloses a method for conducting affinity chromatography to isolate at least one substance, such as protein, from a mixture of substances (see lines 12-40, col. 6). The method comprises the step of affixing affinity ligands to the wells of a microtiter plate, incubating the sample mixture with the ligands, and washing the ligands to remove the unbound species. In light of the disclosure of Hammen, it would have been obvious to one of ordinary skill in the art to utilize immobilized ligands to bind the analyte of interest instead of using functionalized magnetic particles. Immobilized ligands would be easier to process (i.e. perform a wash) than particles that are suspended in the wells.

Claims **9 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of Cortes et al. (US 5,240,604).

Zhang et al. disclose different types of liquid chromatography (e.g. ion-exchange, affinity) to separate a sample mixture, but the reference does not disclose size exclusion chromatography.

Cortes et al. disclose a multidimensional chromatographic system wherein the first dimensional separation is achieved by means of size-exclusion chromatography

conducted in a micro column (see lines 39-65, col. 3). Using this method, the sample can be first separated according to size.

In light of the disclosure of Cortes et al., it would have been obvious to incorporate a size-exclusion chromatography column into the device disclosed by Zhang et al. so that the protein mixture can be separated according to size.

Response to Arguments

Applicant's arguments with respect to the art rejections have been considered but they are moot in view of new grounds of rejection. The amendments changed the scope of the claims and necessitated new grounds of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PSH
11/26/07

Jill Warden
Supervisory Patent Examiner
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